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| APPLICATION NO. |                       | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-----------------------|-------------|-------------------------|---------------------|------------------|
| 10/753,646      | 10/753,646 01/08/2004 |             | Donald J. Davidson      | 5940.US.C3          | 6589             |
| 23492           | 7590                  | 03/18/2005  |                         | EXAM                | INER             |
| ROBERT D        |                       |             | ROBINSON, HOPE A        |                     |                  |
| 100 ABBOT       |                       |             | ART UNIT                | PAPER NUMBER        |                  |
| DEPT. 377/A     | AP6A                  |             | 1653                    |                     |                  |
| ABBOTT PA       | ARK, IL               | 60064-6008  | DATE MAILED: 03/18/2005 |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|--|--|--|--|--|--|--|
|  | Application No.  | Applicant(s)   |  |  |  |  |
| Office Action Summany  | 10/753,646   | DAVIDSON ET AL.  |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit   |  |  |  |  |
| TI MAN INO DATE Afthir committee in  | Hope A. Robinson   | 1653   |  |  |  |  |
| The MAILING DATE of this communication appe<br>Period for Reply  | ears on the cover sheet with the c   | orrespondence address  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period with the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).   | 6(a). In no event, however, may a reply be tim within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | ely filed  will be considered timely.  the mailing date of this communication.  (35 U.S.C. § 133). |  |  |  |  |
| Status   |  |  |  |  |  |  |
| <ul> <li>1) Responsive to communication(s) filed on <u>01 October 2004</u>.</li> <li>2a) This action is <b>FINAL</b>. 2b) This action is non-final.</li> <li>3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</li> </ul>  |  |  |  |  |  |  |
| Disposition of Claims  |  |  |  |  |  |  |
| <ul> <li>4)  Claim(s) 1 and 69-81 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) 1 and 69-81 are subject to restriction and/or election requirement.</li> </ul>   |  |  |  |  |  |  |
| Application Papers   |  |  |  |  |  |  |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the description of the description of the correction and the correction of the order of the correction of the corr | pted or b) objected to by the E<br>rawing(s) be held in abeyance. See<br>on is required if the drawing(s) is obj   | 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list of  | have been received. have been received in Application ty documents have been receive (PCT Rule 17.2(a)).   | on No<br>d in this National Stage  |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  | 4) Interview Summary ( Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:  |  |  |  |  |  |

U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04) Application/Control Number: 10/753,646 Page 2

Art Unit: 1653

## Restriction/Election

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1, 69-74 and 81 are drawn to a compound and composition, classified in class 530, subclass 350.
- II. Claims 75-80 are drawn to a method of treating of a patient in need of anti-angiogenesis therapy, classified in class 514, subclass 2+.
- 2. The inventions are distinct, each from the other because of the following reasons:

Invention I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention I can be used in a materially different process for example, the compound can be used in a process as Kringle 5 is associated with inhibition of *in vivo* tumor growth and reduction of vascular leakage.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Application/Control Number: 10/753,646

Art Unit: 1653

Furthermore, the inventions have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference, which would anticipate the invention of one group, would not necessarily anticipate or make obvious the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, election of a single group for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the

Application/Control Number: 10/753,646

Art Unit: 1653

rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1653

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope A. Robinson Examiner Art Unit 1653

March 15, 2005